

	5 inches).
Claim15 (Original)	The uterine manipulating device of Claim 9 wherein D1 is 1.59 cm (0.625) inches; D3 = 0.95 cm (0.375 inches) and L1 is a distance between 5.08 and 10.16 cm (2 and 4 inches).
Claim16 (Currently Amended)	The uterine manipulating device as in Claim 9 wherein the diameter of the <del>vertical</del> <u>vaginal</u> delineator D4 is a distance of between 3.81 and 6.35 cm (1.5 and 2.5 inches).
Claim17 (Currently Amended)	The uterine manipulating device as in Claim 9 wherein the diameter of the <del>vertical</del> <u>vaginal</u> delineator D4 is a distance of between 4.06 and 5.08 cm (1.6 and 2.0 inches).
Claim18 (Original)	The uterine <u>manipulating</u> device as in claim 9 wherein one end of the handle and one end of the shaft are threaded so as to be removeably attached to each other.
Claim19 (Original)	The uterine <u>manipulating</u> device as in claim 9 wherein one end of the uterine tip and the end of the shaft opposite to the handle are threaded so as to be removeably attached to each other.
Claim 20 (New)	The uterine manipulating device as in claim 2 wherein the uni-body vaginal delineator is in the general shape of a cup, the lip of which seals the vaginal cavity from the uterus.
Claim 21 (New)	The uterine manipulating device as in claim 20 wherein the uni-body vaginal delineator is in the general shape of a cup, the lip of which delineates the surgical incision to be made between the uterus and the cervix.
Claim 22 (New)	The uterine manipulating device as in claim 9 wherein the uni-body vaginal delineator is in the general shape of a cup, the lip of which seals the vaginal cavity from the uterus.
Claim 23 (New)	The uterine manipulating device as in claim 22 wherein the uni-body vaginal delineator is in the general shape of a cup, the lip of which delineates the surgical incision to be made between the uterus and the cervix.

#### **REMARKS/ARGUMENTS**

Original Claims 1-19 remain pending in this Application. Claims 20-23 have been added to better define the vaginal delineator of the present invention. Applicant submits the following as a response to the pending rejections of the Examiner:

#### **A. SPECIFICATION**

Claims 2,7,8,9,16 and 17 were objected to as failing to provide a proper antecedent basis. Applicants have corrected the word “vertical” to “vaginal” as originally intended which does provide a proper antecedent basis.

#### **B. CLAIMS OBJECTIONS**

Claim 12 was objected to because it contained the phrase “wherein the shaft.” The inclusion of the

aforementioned phrase was a typographical error which has been corrected.

### **C. 35 USC §102 REJECTIONS**

The Examiner has rejected Claims 1, 2, 3, 9 and 12 under 35 USC §102(b) as being anticipated by Nicholas (U.S. 5,431,662). According to the Examiner, Nicholas discloses a uterine manipulating device comprising a curved shaft, a handle end, a uterine tip and a vaginal delineator. For anticipation under 35 USC §102(b), the reference must teach every aspect of the claimed invention either explicitly or impliedly. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Nicholas does not teach or disclose a “vaginal delineator.” Nicholas discloses a manipulating device which contains on the distal end a “seal.” As stated beginning on line 8, column 9 of the Nicholas patent, positioned within the entire length of the curved structure is a channel which terminates in the end to be positioned within the uterus, with an opening. On the opposite end, a lue lock is provided for connection to a syringe to administer desired materials such as dyes or markers through the vagina into the uterus. The “seal” in Nicholas is a “stopper” designed to keep fluids inside the uterus. In fact, as shown in Figure 18 of the Nicholas patent, the “seal” looks like a typical “stopper” or “plug.”

The “stopper” or “seal” of the Nicholas patent must be made to slide along the curved structure in order to accommodate differing anatomies. To permit this sliding, the “seal” of the Nicholas patent, as shown in Figure 17 is a complicated multi component mechanism which includes a latch mechanism to fix the “seal” on the curved structure once it has been properly positioned.

The vaginal delineator of the present invention is not a sliding complicated multi component mechanism but is instead of uni-body construction. It is not designed to keep markers and dyes within the uterus as the “seal” in Nicholas is designed to do but rather functions to seal the vaginal cavity. The lip of the cup shaped vaginal delineator of the present invention sits, when properly positioned, on the outside surface of the cervix, not within the uterus cavity as is the case in Nicholas. Most importantly, the vaginal delineator, as its name implies, defines the cut to be made by the surgeon during the hysterectomy procedure. During surgery, the uterine manipulating device of the present invention is pushed up through the vaginal cavity. The vaginal delineator comes into contact with the outside surface of the cervix. As the uterine manipulating device is pushed up in the uterus, the cervix is force into the vaginal delineator. To remove the uterus, the surgeon cuts the cervix along the circumference of the vaginal delineator. Nicholas does not teach or disclose either explicitly or impliedly, that its sliding, complicated multi component seal mechanism is to be used in the manner taught in the present invention and therefore, Claims 1, 2, 3, 9, and 12 of the present invention are not anticipated by such patent, therefore the Examiner’s rejection of such claims should be withdrawn and these claims allowed.

### **D. 35 USC §103 REJECTIONS**

1. The Examiner has rejected Claims 1-3, 7-9, 12, and 16-18 under 35 USC §103(a) as being unpatentable over Rowden (US 5,643,285) in view of Nicholas (US 5,431,662). According to the Examiner, Rowden discloses every aspect of the present invention but the fact that the present invention has a curved shape. Since Nicholas discloses a curved shape, the Examiner has concluded that it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Rowden to include a curved shape.

Interestingly, Rowden is the later patent. Rowden’s perception, as stated in column 1 of his patent, was that there were inherent limitations of the existing uterus manipulating devices with visibility, anatomical

identification and the ability to manipulate organs. The devices Rowden complained of would include those devices in a general curved shaped of a female cervix. Rowden's answer to the limitations of the existing manipulating devices was to create a device with increased strength and leverage that was not curved. In order to allow proper anatomical insertion through the vagina, the end of the Rowden device was allowed to pivot. (Line 10, Column 4). To increase visibility, the "vaginal extender" of the Rowden patent contains "viewing windows." (Line 45, Column 4). Given that Rowden was patented after Nicholas and perceived that the device of the Nicholas patent contained, as discussed above, inherent limitation, one skilled in the art would not have combined Rowden with Nicholas.

The vaginal extender of the Rowden patent will not seal the vaginal cavity because it contains windows. To allow for sealing, Rowden employs the use of a balloon. Rowden, therefore does not disclose every aspect of the present invention except a device of general curved shape. Adding a curved shape to the Rowden device, something Rowden obviously believed should not be done, you would still not end up with the device of the present invention. Sealing of the vaginal cavity would be accomplished using a balloon, which necessitates the need for a way to inflate the balloon. There is no balloon in the present invention and therefore no means to inflate such balloon.

In light of the foregoing, the Examiner's rejection of Claims 1-3, 7-9, 12 and 16-18 should be withdrawn and these claims allowed.

2. The Examiner has also rejected Claims 7, 8, 16 and 17, for the reason that, in light of Rowden, a diameter of 1.5 inches with regards to claims 7 and 16, and a diameter of 1.6 inches with regards to claims 8 and 17 is allegedly obvious. As discussed above, since Rowden does not utilize his vaginal extender to seal the vaginal cavity as is done in the present invention; since Rowden does not utilize a device of curved shape; since Rowden utilizes a balloon for proper sealing, the size limitations of the present invention would not be obvious. In light of the foregoing, the Examiner's rejection of Claims 7, 8, 16 and 17 should be withdrawn and these claims allowed.

3. The Examiner has also rejected Claims 10 and 11, as being unpatentable over Rowden and Nicholas as applied to Claim 1 above and in further view of Harris (US 4,430,076), for the reason that the modified device of Rowden discloses the invention substantially as stated but fails to disclose a diameter of 2.54 cm for the handle. As previously stated in this response, Rowden combined with Nicholas does not substantially state the present invention. For such reason, the Examiner's rejection of Claims 10 and 11 should be withdrawn and these claims allowed.

4. The Examiner has also rejected Claims 4 and 13, as being unpatentable over Rowden and Nicholas as applied to Claim 1 above and in further view of Fox (US 5,437,628), for the reason that the modified device of Rowden discloses the invention substantially as stated but fails to disclose a radius of curvature of 6 inches. As previously stated in this response, Rowden combined with Nicholas does not substantially state the present invention. For such reason, the Examiner's rejection of Claims 4 and 13 should be withdrawn and these claims allowed.

5. The Examiner has also rejected Claim 19, as being unpatentable over Rowden and Nicholas as applied to Claim 1 above and in further view of Hasson (US 5,562,680), for the reason that the modified device of Rowden discloses the invention substantially as stated but fails to disclose that the uterine tip and the end of the shaft opposite to the handle are threaded so as to be removably attached to each other. As previously stated in this response, Rowden combined with Nicholas does not substantially state the present invention. For such reason, the Examiner's rejection of Claim 19 should be withdrawn and these claims

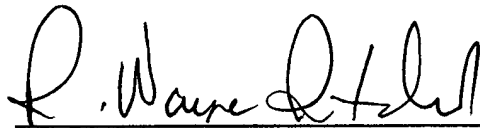
allowed.

6. The Examiner has also rejected Claims 5, 6, 14 and 15, as being unpatentable over Rowden and Nicholas as applied to Claim 1 above and in further view of Smith (US 6,423,075), for the reason that the modified device of Rowden discloses the invention substantially as stated but fails to disclose values for the diameter of the shaft, the diameter of the uterine tip, or the length defined by the distance between the end of the uterine tip and the vaginal delineator. As previously stated in this response, Rowden combined with Nicholas does not substantially state the present invention. For such reason, the Examiner's rejection of Claims 5, 6, 14 and 15 should be withdrawn and these claims allowed.

#### **Conclusion**

Applicants believe that the amendments made herein both correct the typographical errors noted by the Examiner as well as highlight the differences between the present invention and the art cited by the Examiner. Applicants believe that all claims are now directed to allowable subject matter. For the convenience of the Examiner a clean version of the revised claims are attached hereto as Exhibit "A" and incorporated by reference for all purposes. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "R. Wayne Pritchard", is written over a horizontal line.

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